REMARKS/ARGUMENTS

Claims 56-63 are pending in this patent application. All pending claims currently stand rejected. In this response the Applicant has canceled claims 56 and 58. Claim 59 now refers to claim 57 to remove the dependence on a canceled claim. No new claims have been added. Thus, the Applicants respectfully submit that no new matter has been included in this response.

The present claims relate to combinations of compounds for lowering serum cholesterol levels. Together these combinations of compounds show a synergistic effect not observed when the components are used alone.

Response to Rejection of Claims 56 and 58-60 under 35 U.S.C. §112, first paragraph

The rejection of Claims 56 and 58-60 under 35 U.S.C. §112, first paragraph as being unsupported by the written description is rendered moot by the cancellation of claim 56

Claim 56 has been canceled. Claim 57 was not rejected on this ground. Claims 59-63 originally depended from claim 57 so their inclusion in the rejection appears to be in error. All claims remaining in the application upon entry of this response now depend either directly or indirectly from Claim 57. Thus, the Applicants submit that the current claims are supported by the written description.

Response to Rejection of Claims 56-63 under 35 U.S.C. §103

The rejection of claims 56-63 under 35 U.S.C. §103 based on the combination of EP 952208, US5952393, US6596776, US4495094, US6394230 and the Jones et al. reference is improper because there is no evidence in the references that particular combinations of components would have an improved effect greater than the sums of the individual effects of the components.

Applicants have reviewed the disclosure of the cited references and respectfully disagree that the disclosures therein destroy the patentability of the claims. Our detailed reasons follow.

A prima facie case of obviousness requires that the references or combination thereof disclose each and every element of the claim and that there be some reason to combine the references to arrive at the claimed invention. Thus we start our analysis with the disclosures of the references.

EP 952208 fails to disclose compositions having hexacosanol and tetracosanol concentrations in the claimed ranges. For example, each of the compositions disclosed in the cited examples has less than 1% hexacosanol while the claims recite a concentration of at least 15% to 50%. The tetracosanol concentration is also low, less than 5%, while the claims recite a range of 20% to about 60%. Instead, the compositions of the EP952208 reference have high concentrations of beta-sitosterol and sterol esters, with only minor amounts of the remaining claimed components. Thus, this disclosure combined with the cited general teaching that stanols may be useful for lowering cholesterol is insufficient to destroy the patentability of the specifically claimed ranges.

US5952393 requires both a policosanol and a phytosterol to be present in the composition. And like EP 952208, the policosanols disclosed as useful have no more than 3.21 % of tetracosanol while the claims require at least 20%. In addition, the policosanol mixtures described therein have only 0.36% docosanol while the claims require from 20% to 60% docosanol. Thus, US 5952393 also fails to disclose compositions having the claimed proportions. And due to the extremely low concentrations, one skilled in the art would not have a reasonable expectation that a composition comprising such drastically different concentrations would be effective.

US6596776 discloses compositions that again have only from 0-5% docosanol. There is no indication that compositions having at least 4 times this amount would be beneficial or effective.

Thus, each of these references fails to teach the claimed composition, most particularly with respect to the very much larger concentrations of tertacosanol and docosanol. Specifically, none of the references disclsoes that compositions having from 20-60% docosanol will be effective in lowering cholesterol. The optimization of ranges as obvious based on routine experimentation cannot be applied to compositions which essentially fail to include one or more major components. In the absence of some motivation, routine optimization cannot be relied on to destroy patentability of compositions having a 300% to 1100% increase in the concentration of the docosanol concentration,

as required by the present claims. Thus, the combination of references does not destroy the patentability of claim 57.

The remaining references appear to be relied upon to disclose the incorporation of policosanols in food products. Applicants respectfully assert that these references also fail to disclose the claimed compositions and fail to cure the above described deficiencies. Thus, the combination of references does not destroy the patentability of claim 57.

CONCLUSION

Applicants have addressed all of the Examiner's rejections. Applicants believe that the claims are now in condition for allowance and respectfully request that the Examiner grant such an action. If any questions or issues remain in the resolution of which the Examiner feels will be advanced by a conference with the Applicants' attorney, the Examiner is invited to contact the attorney at the number noted below. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 50-3420, reference 22106965-105181 (Friedrich).

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Respectfully submitted,

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